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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/036,681

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David G. Barkalow

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7590

07/03/2002

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,681

Applicant(s)

BARKALOW ET AL.

Examiner

Humera N Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 19 is/are rejected.
- 7) ☒ Claim(s) 17 and 18 is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the IDS filed 02/14/02 and the IDS filed 02/15/02.

Claims 1-24 are pending. Claims 1-24 are subject to an Election and/or Restriction requirement.

After a provisional election *without* traverse, claims 1-19 are pending. Claims 20-24 have been withdrawn. Claims 1-19 are rejected.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to a pullulan free edible film composition and a method of treating halitosis, classified in class 424, subclass 49.
- II. Claims 21 and 22, drawn to a method of treating xerostomia, classified in class 424, subclass 49.
- III. Claims 20, 23 and 24, drawn to a method of treating plaque or gingivitis, classified in class 424, subclass 49.

During a telephone conversation with Robert M. Barrett on 06/26/02 a provisional election was made *without* traverse to prosecute the invention of Group I, claims 1-19.

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Affirmation of this election must be made by applicant in replying to this Office action.

Claims 20-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claims 17 and 18 are objected to because of the following informalities:

Claims 17 and 18 have not been further treated on the merits since they depend upon a non-elected claim that has been withdrawn from consideration. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 10, 12, 15, 16 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "includes" in claims 10, 12, 15, 16 and 19 is indefinite because it is unclear which additional components aside from the medicament, additive, thickening agent and breath freshening agent are contained in the pullulan free edible composition. It is suggested that the term "includes" be deleted and be positively recited with a term such as "comprising".

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because a preceding claim cannot depend on a succeeding claim (claim 18). Appropriate correction is required.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it is confusing and unclear as to what the applicant is intending to claim with the use of the terms "edible polymer and a land plant extract and derivatives thereof and combinations thereof." Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Zerbe *et al.* (US Pat. No. 5, 948,430).

Zerbe *et al.* disclose a water-soluble film composition for oral administration comprising a film-forming agent, filler and a plasticizer in the instantly claimed percentages (see reference column 2, lines 14-67); (column 3, lines 1-61) and examples.

Claims 1-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwakura *et al.* (US Pat. No. 4,777, 046).

Iwakura et al. disclose a preparation in the form of a film for oral cavity administration comprising a film-forming agent, filler and a plasticizer in the instantly claimed percentages (see entire reference).

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazard et al. (EPO 0 547 551 A1).

Lazard et al. disclose edible film compositions comprising a film-forming agent, filler and a plasticizer in the instantly claimed percentages (see reference pages 1-5, 8-9) and claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al. (US Pat. No. 5, 948,430).

Zerbe et al. while teaching a water-soluble film composition for oral administration comprising a film-forming agent, filler and a plasticizer do not explicitly teach a method of treating halitosis. However Zerbe et al. disclose a composition comprising breath freshening agents for use in the oral cavity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use

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a combination of a film-forming agent, filler and plasticizer and a breath-freshening agent for use in the oral cavity because it improves the general odor originating from an individual's mouth and effectively reduces malodors. The expected result would be an odor-reducing film preparation for oral administration.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600